

- Challenges in maintaining a compliant computerized information system.

FINAL EXAM: Upon completion of the four course modules, end users are required to complete a 10-question, multiple choice final exam. The exam (an Adobe .pdf file) is located at the end of the Course 103 module after the practice set of exam questions for that module. Each end user must complete the exam and submit an electronic or hard copy to the MeRITS PMO. To receive an account on any MeRITS PMO regulated system, end users must pass this exam with an 80% or above.

What happens if I do not complete the training?

Personnel who do not complete the Course 100 Series Training Program will not be granted user accounts or passwords for information systems as they are introduced across the Command. Users must be able to achieve a score of 80% or above on the final exam.

How can I obtain the Course 100 Series Training?

The Course 100 Series Training Program via CD-ROM is available from the MeRITS PMO. If you would like to obtain a copy of the CD-ROM, or if you have any questions, concerns or comments, please send your contact information directly to:

USAMRMC.MeRITS@amedd.army.mil

A note from the MeRITS PMO...

We realize that information technology and the data that is generated is taken for granted due to the ubiquitous nature of technology and the rapid pace and demands during research efforts.

The Course 100 Series Training Program is a first, but critical step in educating Command personnel on the intersection of research and information technology, as well as the rigors and requirements required of industry and non-commercial research entities alike. There is no exception. We must train for the future and take a prospective posture on the protection of our most valuable asset ~ our information.



Protect, Project, Sustain

MeRITS PMO

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USAMRMC, MeRITS Regulatory Information Systems Course 100 Series Training Program

FAQs



Revised April 2006

Course 100 Series Training Program FAQs

What is it?

The United States Army Medical Research and Materiel Command (USAMRMC), MeRITS Regulatory Information Systems Course 100 Series Training Program provides basic regulatory information systems instruction as it pertains to the FDA-regulated activities you perform everyday. The program consists of four modules and a 10-question, multiple choice final exam.

Who needs it?

Any individual conducting FDA-regulated activities should complete the program. It is a prerequisite for any MeRITS PMO regulated system, including FRED (FDA Regulated Electronic Documents). This training, and documentation of this training, is also required by 21 Code of Federal Regulations (CFR) Part 11 and the associated predicate rules.

What are the benefits and what will I learn?

USAMRMC expends substantial funds and years of scientific effort conducting research. The FDA grants product licensure based on the integrity, completeness, scientific accuracy, and reliability of the information generated by this research. Therefore, our information must have integrity and be properly managed across the diverse spectrum of product development stages and activities to receive FDA approval.

The development of a Command-wide understanding, and adoption of common practices and procedures will enable USAMRMC to fulfill regulatory obligations concerning the collection, creation, and management of research information as required from all research institutions engaged in conducting clinical trials and/or research leading to clinical trials. This training will help achieve this by providing personnel with a better understanding of:

- Our unique product development life cycle.
- Who generates regulated information, as well as where and how it is generated.
- How the completeness and accuracy of our data is crucial to attracting and engaging commercialization partners.
- Why the integrity, completeness, accuracy, and secure management of regulated information is critical in light of FDA requirements today.
- Emerging technology and dramatic shifts in the submission and review of regulatory product dossiers to the FDA and world-wide authorities.
- A basic information principle: *If it isn't written down, it didn't happen; however, once it is written and recorded electronically, it is memorialized for long retention periods (records), discoverable during audits and/or legal inquiries and therefore, must be complete, accurate and trustworthy.*

How do I complete the training?

To complete the Course 100 Series Training Program, end users are required to complete all four modules (Courses 100-103) of the series and the final exam. A description of each module and the final exam are provided below:

COURSE 100: An Overview of FDA-Regulated Activities, Information, and Systems

- An introduction to the FDA's oversight role in product development, compliance and key regulations.
- FDA expectations and how USAMRMC strives to meet them through documentation and the use of computerized information systems.
- A brief introduction to key FDA-regulated activities concerning computerized information systems, and Regulations governing information and records.

COURSE 101: Relating FDA Regulations to USAMRMC Regulated Activities

- Insights regarding the relationship of specific FDA regulations to functional areas and roles.
- Performance of key regulated activities.
- Management of regulated information assets.

COURSE 102: Understanding Information Assets in FDA Regulated Settings

- The differences between data, documents and records.
- The information development life cycle.
- Examples of USAMRMC regulated documents and records.
- Information regarding electronic records and electronic signatures.

COURSE 103: Introduction to Regulated Computerized Information Systems

- An overview of information technology used in product research and development.
- The general features of document management, clinical data management, laboratory information, and adverse event reporting systems.
- A brief overview of system testing, validation and implementation.